



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/644,680 | 08/20/2003 | Kevin J. Frank | 5074A-000064 | 6450 |
| 27572 | 7590 | 04/08/2008 | EXAMINER | |
| HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303 | | | | SMITH, JEFFREY S |
| ART UNIT | | PAPER NUMBER | | |
| 2624 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 04/08/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/644,680 | FRANK ET AL. | |
| | Examiner | Art Unit | |
| | JEFFREY S. SMITH | 2624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 December 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16, 18-26 and 28-51 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 16, 18-26, 37-42 and 45-51 is/are allowed.
 6) Claim(s) 1-7, 10, 12-15, 28-30, 32-35, 43 and 44 is/are rejected.
 7) Claim(s) 8-9, 11, 31, 36 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 18 December 2007 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penney et al. "Validation of a two- or three-dimensional registration algorithm for aligning preoperative CT images and intraoperative fluoroscopy images" ("Penney") in view of the Series 9600 Mobile Digital Imaging System ("9600"), U.S. Patent Number 6,118,845 issued to Simon et al. ("Simon") and U.S. Patent Number 6,381,485 issued to Hunter et al. ("Hunter").

For claim 1, Penney discloses a method for registering two-dimensional image data with three-dimensional image data of a body of interest (abstract), said method comprising: acquiring the three-dimensional image data having first patient orientation information (abstract); acquiring the two-dimensional image data having second patient orientation information (abstract); and generating a digitally reconstructed radiograph that substantially corresponds to the two-dimensional image data using the three-dimensional image data and the first and second patient orientation information (abstract). 9600 discloses an imaging system that can perform the method of Penney.

Simon discloses a method for acquiring patient orientation information including determining how that patient was positioned or oriented relative to an imaging device during acquisition of the data (abstract).

Hunter discloses a method of determining an estimate of the patient's orientation with respect to a dynamic reference frame based in part on a known relation to at least one structure (col. 3 lines 37-57).

It would have been obvious to one of ordinary skill in the art at the time of invention to include the calibration information of Simon and the dynamic reference frame of Hunter with the 9600 to achieve the predictable results of calibrating and registering the images. It also would have been obvious to one of ordinary skill in the art at the time of invention to use the calibration markers of Simon as the plurality of reference points in known relation to a structure in Hunter to achieve the predictable results of determining an estimate of the patient's orientation with respect to a dynamic reference frame, and including a view through the three dimensional image data, along the direction of the two dimensional image data based upon the orientation information determined by Simon and Hunter.

For claim 2, Penney discloses a PA view and a RAO view as shown in figure 2. The Series 9600 discloses a device for acquiring a two-dimensional anterior to posterior image and a two-dimensional lateral image. It would have been obvious to one of ordinary skill in the art at the time of invention to use the 9600 to acquire the digital images for the benefit of generating a DRR which aids in treating patients as taught by Penney on page 1024.

For claim 3, Penney discloses identifying a center of a body of interest in the two-dimensional anterior to posterior image and the two-dimensional lateral image as discussed on page 1029.

For claim 4, Penney discloses generating a digitally reconstructed radiograph further includes generating an anterior to posterior digitally reconstructed radiograph and a lateral digitally reconstructed radiograph corresponding to the two-dimensional anterior to posterior image and the two-dimensional lateral image as discussed in section 2.

For claim 5, Penney discloses identifying a center of the body of interest in the anterior to posterior digitally reconstructed radiograph and the lateral digitally reconstructed radiograph as discussed in section 2.

For claim 6, Penney discloses identifying a common point in the three-dimensional image data with the two-dimensional image data using the identified centers of the anterior to posterior image, lateral image, anterior to posterior digitally reconstructed radiograph image and lateral digitally reconstructed radiograph image as shown in figure 2.

For claim 7, Penney discloses refining the registration of the two-dimensional image data with the three-dimensional image data using the first and second patient orientation information and the common point information as shown in figure 2.

For claim 10, Penney discloses adjusting a registration window on the body of interest in each anterior to posterior image, lateral image, anterior to posterior digitally reconstructed radiograph image, and lateral digitally reconstructed radiograph image,

wherein only the image data within the registration windows are used for refined registration as discussed in section 2.

For claim 14, Penney discloses performing multiple registrations on multiple bodies of interest.

For claim 15, Penney show the body of interest is a vertebrae.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penney in view of Series 9600, Simon and Hunter as applied to claims 1-7 and 10 above, and further in view of Penney et al. "A Comparison of Similarity Measures for Use in 2-D-3-D Medical Image Registration" ("Penney II").

For claim 12, Penney II shows performing a refinement registration utilizing normalized mutual information and pattern intensity as discussed in section 3. It would have been obvious to one of ordinary skill in the art at the time of invention to use the similarity measures of Penney II when generating the DRR of Penney for the benefit of increasing the accuracy of registration as taught by Penney II in the abstract.

For claim 13, Penney II discloses optimizing the refinement registration by utilizing a multi-stage steepest ascent algorithm.

Claims 28-30 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penney in view of Series 9600, Simon and Penney II.

For claim 28, Penney and Series 9600 disclose acquiring the three-dimensional image data of the body of interest; acquiring a two-dimensional image of the body of

interest; Penney discloses generating a digitally reconstructed radiograph that substantially corresponds to the two-dimensional image; Simon discloses performing intensity adjustment of the two-dimensional image to reduce the effect of an interfering object (col. 6 lines 8-49); and Penney and Penney II disclose aligning the two-dimensional image with the digitally reconstructed radiograph using a similarity/cost measure. It would have been obvious to one of ordinary skill in the art at the time of invention to apply the intensity adjustment of Simon with the image acquisition method of Penney, 9600 and Penney II for the benefit of removing calibration markers from the image as taught by Simon in the abstract.

For claim 29, Penney discloses the two-dimensional image of the body of interest is a two-dimensional lateral image.

For claim 30, Penney discloses acquiring a two-dimensional anterior to posterior image and generating an anterior to posterior digitally reconstructed radiograph that substantially corresponds to the anterior to posterior image.

For claim 32, Penney and Penney II disclose acquiring the three-dimensional image data further includes acquiring first patient orientation information, wherein acquiring the two-dimensional lateral image and the two-dimensional anterior to posterior image further includes acquiring second patient orientation information, and wherein generating the digitally reconstructed radiographs further includes generating the lateral digitally reconstructed radiograph and the anterior to posterior digitally reconstructed radiograph using the three-dimensional image data and the first and second patient orientation information.

For claim 33 Penney discloses identifying a center of the body of interest in the two-dimensional anterior to posterior image and the two-dimensional lateral image.

For claim 34 Penney discloses identifying a center of the body of interest in the anterior to posterior digitally reconstructed radiograph and the lateral digitally reconstructed radiograph.

For claim 35 Penney discloses identifying a common point in the three-dimensional image data with the two-dimensional image data using the identified centers of the anterior to posterior image, lateral image, anterior to posterior digitally reconstructed radiograph image and lateral digitally reconstructed radiograph image.

Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penney in view of Series 9600, Simon and Penney II as applied to claim 28 above, and further in view of U.S. Patent Number 6,282,261 issued to Mazess et al. ("Mazess").

For claims 43-44, Mazess discloses determining a histogram of intensity of the two dimensional image (figure 13), determining a mean of the intensity (figure 16), and adjusting the mean of the intensity to a target value (figure 16), wherein adjusting the mean includes adjusting the contrast, the brightness, the level, or the width, or combinations thereof (figures 15-17).

Response to Arguments

With respect to the information disclosure statement, applicants submit portions of the MPEP that fail to address the submission of over 700 prior art references, while

ignoring the relevant section of the MPEP 2004 that specifically addresses the submission of over 700 prior art references:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance.

This statement is made as a courtesy to applicants to give applicants a chance to identify the material portions of significant references during prosecution. Applicants may choose to ignore this. However, applicants appear to be under the impression that the materiality of each reference has been considered by the Office by stating that "the Examiner's initials next to all of the citations indicates that all of the references cited by applicants have been considered in the same manner as other documents in Office search files."

Applicants are wrong in presuming that the Examiner's initials means that the material portions of all of the references have been considered. Applicants are correct in that the citations have been considered in the same manner as other documents in Office search files. What this means, as stated in the previous Office action, is that only the titles of the references have been considered, with the exception of the portions of the references specifically cited in the Office actions. This is consideration in the same manner as other Office files that contain hundreds upon hundreds of documents. Beyond this, the materiality of the references has not been considered and will not be considered unless applicants explicitly identify specific portions of specific references

such as those which "have been specifically brought to applicant's attention and/or are known to be of most significance."

Allowable Subject Matter

Claims 8-9, 11, 31 and 36 and are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 16, 18-26, 37-42 and 45-51 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The art of record does not disclose a registration method for registering three dimensional images with two dimensional images using two similarity/cost measures. The art of record discloses registration using one similarity/cost measure. The use of at least two similarity/cost measures is novel over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY S. SMITH whose telephone number is (571)270-1235. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu can be reached on 571 272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSS
March 31, 2008
/Jingge Wu/

Supervisory Patent Examiner, Art Unit 2624